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IS 3317 (2004): Hypodermic needles-Reusable type-Specification [MHD 1: Surgical Instruments]

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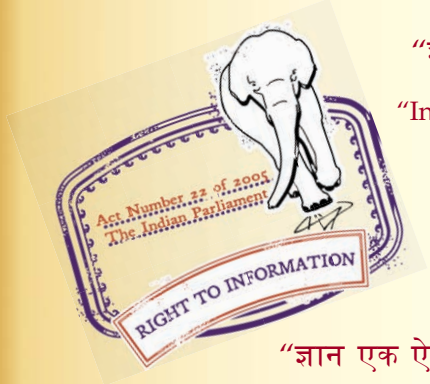

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"Knowledge is such a treasure which cannot be stolen"

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भारतीय मानक

पुनःउपयोग टाइप की अधोत्वचीय सुइयाँ — विशिष्टि

(दूसरा पुनरीक्षण)

Indian Standard

HYPODERMIC NEEDLES, REUSABLE TYPE — SPECIFICATION

(Second Revision)

ICS 11.040.20

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BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

November 2004

Price Group 4

Medical Instruments and Disposables Sectional Committee, CHD 35

FOREWORD

This Indian Standard (Second Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Medical Instruments and Disposables Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

After dissolution of Medical Equipments and Hospital Planning Division Council, the work of Medical Instruments and Disposable Sectional Committee, was transferred to Chemical Department under the newly constituted Medical Instruments and Disposables Sectional Committee.

This standard was first published in 1965 and revised in 1983 to align it with ISO Recommendation No.741 for hypodermic needles and to incorporate six amendments issued from time-to-time in order to effect various modifications based on the experience gained due to implementation of this standard and align it with the latest practice being followed by the industry at the national as well as international level.

This standard has been undertaken with a view to rationalize the bore sizes, modification of angle of the needle point and incorporate certain other requirements, such as, stiffness, patency of lumen and test for resistance to breakage in the preparation of this revision, assistance has been derived from ISO 7864 : 1993 'Sterile hypodermic needles for single use'.

The composition of the Committee responsible for formulation of this standard is given in Annex C.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the results of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

HYPODERMIC NEEDLES, REUSABLE TYPE — SPECIFICATION

(Second Revision)

1 SCOPE

This standard covers reusable hypodermic needles of luer type conical fittings, both for luer male donical fittings and luer lock type male conical fittings used with hypodermic and luer type syringes and some other medical instruments used for giving injections (subcutaneous, intramuscular, intravenuous, etc).

2 REFERENCES

The standards listed below contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revisions and parties to agreements based on this standards are encouraged to investigate the possibility of applying the most recent editions of the standard indicated below:

IS No.	*Title*
1570 (Part 5) : 1985	Schedule for wrought steels: Part 5 Stainless and heat resisting steels (*second revision*)
2500 (Part 1) : 2000	Sampling inspection procedures: Part 1 Attribute sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection (*third revision*)
3234	Conical fitting with a 6% (luer) taper for syringes, needles and certain other medical equipment:
(Part 1) : 1986	General requirements (*second revision*)
(Part 2) 1995	Lock fittings (*second revision*)
4905 : 1968	Methods for random sampling
8364 : 1989	Free cutting brass wire (*first revision*)

3 TERMINOLOGY

For the purpose of this standard, the following definitions shall apply.

3.1 Length of Needle — The exposed length of needle tube measured from the tip of the point to the junction with hub. It is also known as cannula.

3.2 Point (or a Bevel) — The bevelled portion of the end suitably bevelled and sharpened.

3.3 Angle of Point — The angle of bevel to the longitudinal axis of the needles.

3.4 Hub (or Lumen) — The metal component having the conical taper on which the needle is fixed on the longitudinal axis.

3.5 Bore (or Lumen) — The internal diameter of the needle tubing.

3.6 Luer Type Conical Fitting — Female taper of the hub of the needle.

3.7 Stillette — The wire supplied with hypodermic needles for cleaning the lumen.

4 MATERIAL

4.0 The various components of hypodermic needles shall be made from the following materials.

4.1 Cannula

The cannula shall be made from stainless steel tubing conforming to class AISI-304, C04 Cr18 Ni 1 1 of IS 1570 (Part 5) or any other suitable grade of stainless steel.

4.2 Hub

The hub shall be made from free cutting brass wire conforming to IS 8364 and plated nickel or chromium.

4.3 Stillette

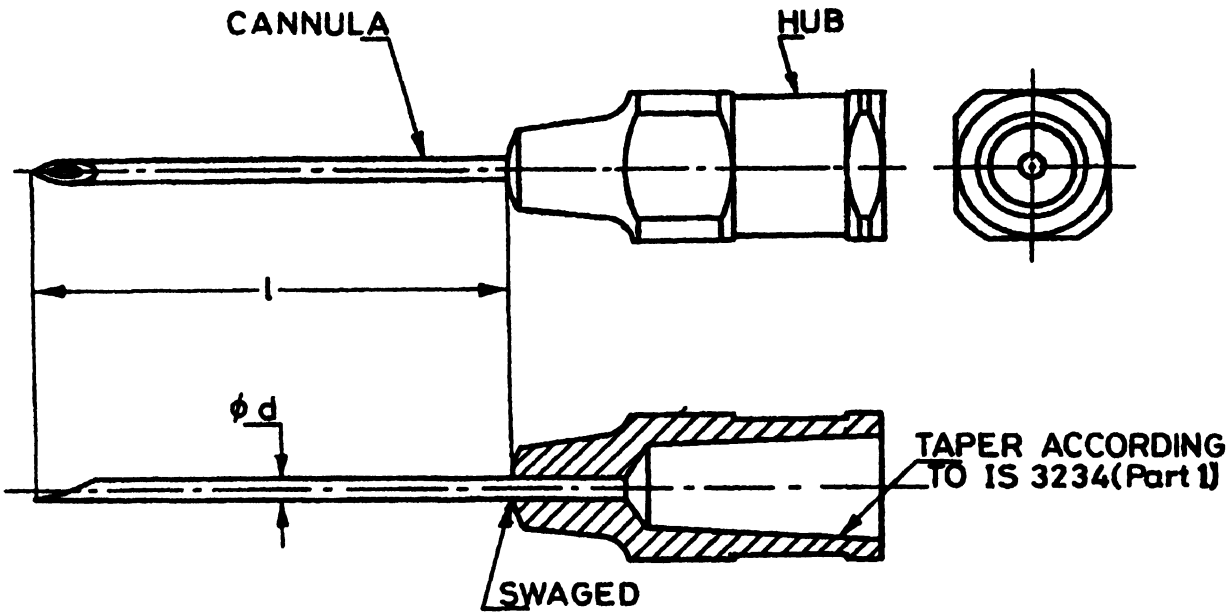
The stillette shall be made from hard-drawn brass wire or stainless steel wire and supplied one for each needle.

5 CONICAL FITTING

The conical fitting shall be of the luer type and shall be in accordance with IS 3234 (Part 1) and IS 3234 (Part 2).

6 SHAPE AND DIMENSIONS

6.1 The needle may confirm to the shape given in Fig. 1 and dimensions as given in Table 1. The needles may have other diameter length combinations as agreed to between the purchaser and the supplier. However, the minimum length of hub shall be 11.0 mm.



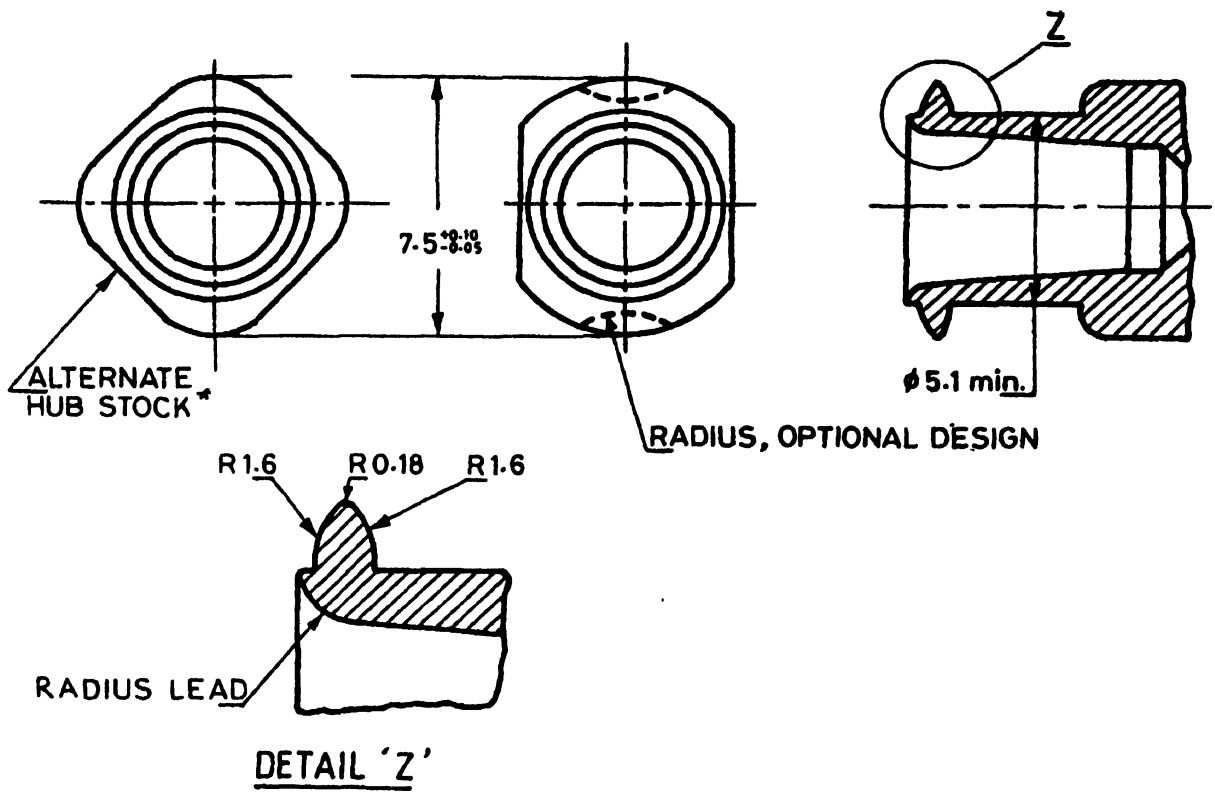
NOTE — For dia *d* and length *l* *see* Table 1.

FIG. 1 HYPODERMIC NEEDLE

Table 1 Sizes and Dimension of Cannula of Reusable Hypodermic Needles
(*Clauses* 6.1 *and* 6.2)
All dimensions in millimetres.

Sl No.	Designations of the Needle	Outside Diameter of the Needle Tubing (Nominal Diameter) Tolerance ± 0.04	Bore of the Needle, *Min*	Length of Needle Tube					
				12.5	16.0	20.0 +1.0 −2.0	25.0	31.8 +1.5 −2.5	38.0
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
i)	4	0.40	0.18	X	X	X	X		
ii)	4.5	0.45	0.20	X	X	X	X		
iii)	5	0.50	0.20	X	X	X	X		
iv)	5.5	0.56	0.28		X	X	X	X	X
v)	6	0.63	0.28		X	X	X	X	X
vi)	7	0.71	0.35			X	X	X	X
vii)	8	0.80	0.46			X	X	X	X
viii)	9	0.90	0.52			X	X	X	X
ix)	10	1.00	0.56					X	X
x)	12	1.25	0.71						X
xi)	14	1.45	0.86						X
xii)	16	1.60	1.10						X
xiii)	18	1.80	1.20						X
xiv)	20	2.00	1.24						X
xv)	25	2.50	1.31						X

NOTE — X indicates recommended diameter-length combinations.



NOTE — Detail at *Z* is optional design. Other shapes permitted.

All dimensions in millimetres.

FIG. 2 LUER LOCK CONNECTIONS, FEMALE

6.2 The normal diameter of the needle shall be designated by a number closely corresponding to the outside diameter of the cannula (*see* Table 1).

6.3 The length of stillette shall be minimum 10 mm more than the overall length of the needle (that is, length of cannula plus length of hub).

7 UNION BETWEEN THE HUB AND THE NEEDLE TUBE

The cannula shall be pushed well into the cavity of the hub but not extending into the conical portion and securely swaged. The cannula and the hub shall be concentric and well aligned as agreed to between the manufacturer and the purchaser.

8 NEEDLE POINT

8.1 The needle point shall be one of the following types:

a) Long bevel, 12 ± 2° to axis;
b) Short bevel, 18 ± 2° to axis; and
c) Any other angle subject to a tolerance of ± 2°.

8.2 The needle point shall be sharpened on three aspects as shown in Fig. 3. It shall be well defined, free from feather edges, irregularity, burrs, hooks and other defects, when examined under 10 X to 15 X magnification.

9 FINISH

9.1 Cannula shall be smooth both outside and inside and free from pits, tool marks, burrs and foreign matter.

9.2 The hub shall be nickel or chromium plated both inside and outside and polished. The plating shall be such as to withstand the corrosion resistance test prescribed in **10.9**.

10 TESTS

10.1 Stiffness Test

Support the cannula of the needle at two places giving a span as shown in Table 2, and load it centrally as specified for 1 s approximately. The deflection of the cannula shall be not greater than the limits given in Table 2. For needle sizes other than those specified in Table 2, the deflection shall be as agreed to between the manufacturer and the purchaser.

10.2 Resistance to Breakage

When tested in accordance with the method given in Annex A, the needle tube shall with stand 20 complete cycles of reversal of force without breaking.

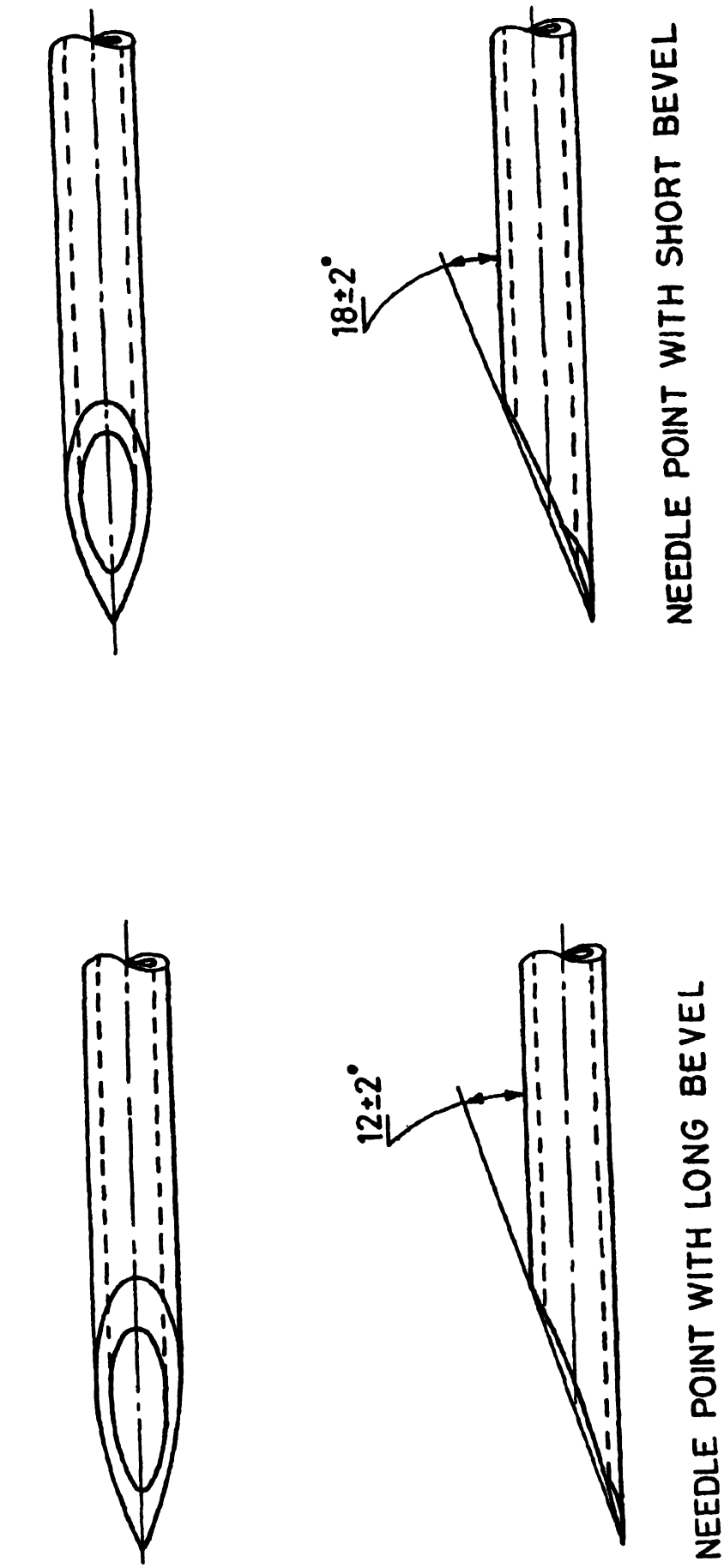


FIG. 3 POINTS OF HYPODERMIC NEEDLE WITH LONG AND SHORT BEVELS

Table 2 Tests
(*Clauses* 10.1, 10.6, 10.7 *and* 10.8)

Sl No.	Diameter of Cannula	Elasticity		Reverse Bend Test		Stiffness			
		Contact Distance from Hub	Angle of Bend	Contact Distance from Hub	Deflection	Separation of Test Edge	Load	Deflection *Max*	Security of Swaging Pull to be Applied *Min*
	mm	mm	Degree	mm	Degree	mm	g	mm	kg
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
i)	0.40	8	12	8	30	10	550	2.5	2.00
ii)	0.45	9	12	9	25	10	600	2.2	2.25
iii)	0.50	11	12	11	25	12	700	2.0	2.50
iv)	0.56	14	12	14	25	14	900	1.8	3.00
v)	0.63	16	12	16	25	15	1 100	1.6	3.50
vi)	0.71	17	12	17	25	15	1 250	1.6	4.00
vii)	0.80	19	12	19	25	15	1 400	1.2	4.50
viii)	0.90	25	12	25	25	20	1 500	1.0	5.50
ix)	1.00	29	12	29	25	25	2 000	0.9	6.50
x)	1.25	32	12	32	25	25	2 000	0.8	6.50
xi)	1.45	32	12	32	25	25	2 100	0.8	—
xii)	1.60	32	9	—	—	25	2 200	0.9	9.00
xiii)	1.80	32	9	—	—	25	2 200	0.7	—
xiv)	2.00	32	7	—	—	25	2 500	0.5	9.00
xv)	2.50	32	5	—	—	25	2 500	0.5	9.00

10.3 Patency of Lumen

A stainless steel stillette of the appropriate diameter selected from Table 3 shall pass through the needle.

Alternatively, the lumen shall satisfy a water flow rate test in which the flow rate shall be not less than 80 percent of that of a needle of equivalent diameter and length with a minimum bore in accordance with Table 1. The water pressure during the test shall not exceed 1×10 Pa (1 atm).

Table 3 Diameter of Stillette
(*Clause* 10.3)
All dimensions in millimetres.

Sl No.	Nominal External Diameter	Diameter of Stillette, *Min*
(1)	(2)	(3)
i)	0.40	0.15
ii)	0.45	0.18
iii)	0.5	0.18
iv)	0.55	0.23
v)	0.6	0.23
vi)	0.7	0.27
vii)	0.8	0.38
viii)	0.9	0.45
ix)	1.0	0.45
x)	1.2	0.45
xi)	All higher sizes above 1.2	0.50

10.4 Leakage Test

Fit the needle to a tested syringe and connect the syringe to a water source on which pressure could be exerted. Run water through the needle to eliminate air, seal the assembly outlet and bring the water pressure to 300 kPa. Maintain the pressure for 30 s. There shall be no leakage sufficient to form a falling drip. The conical fitting under test shall be horizontal.

10.5 Sharpness of Needle Point

Take an aluminium foil 0.02 mm thick and clean it with alcohol or benzene and mount suitably so that it spread taut and the needle may penetrate vertically. Hold the needle vertically with the point touching the foil. Apply load on the hub gently starting with 1 g. Then increase the load gradually, so as to reach the test load in about 30 s. The needle shall penetrate the aluminium foil with a test load not exceeding 30 g.

10.6 Elasticity

After removal, clamp the hub rigidly and deflect the cannula through an angle given in Table 2, sufficient force being applied at a contact distance as specified in Table 2. With the applied force, the needle shall show no permanent set or damage. For needle sizes other than those specified in the Table 2, the contact distance and deflection shall be as agreed to between the manufacturer and the purchaser.

10.7 Reverse Bend Test

Clamp the hub firm and apply a sufficient force at points whose contact distance is in accordance with the requirements of Table 2, so that the cannula is

deflected through the degrees specified and reverse the test on the opposite direction. Repeat the test 20 complete cycles and examine the needle. The needle shall have suffered no damage and no sign of fracture developed. For needle sizes other than those specified in Table 2, the contact distance and deflection shall be as agreed to between the manufacturer and the purchaser.

10.8 Security of Swaging

The swaging of the cannula with the hub shall be tested by applying for 1 min a pull of magnitude shown in Table 2. The cannula shall not come out of the hub and it shall not become loose. For needle sizes other than those specified in Table 2, the pull shall be as agreed to between the manufacturer and the purchaser.

10.9 Corrosion Resistance

The complete needle shall be immersed in a 10 percent solution of citric acid at room temperature for 5 h. It shall then be boiled in distilled water for 30 min and cooled while immersed in the same for 48 h. The cannula or the hub shall show no corrosion. The test shall be conducted in a glass container.

10.10 Freedom from Foreign Matter

The cannula and the hub shall be examined under good illumination with a magnifying lens; they shall be free from foreign matter, metal particles or chips, pits, burrs and other defects.

11 PACKING AND MARKING

11.1 Packing

Needle shall be packed in accordance with accepted trade practices and supplied with equal number of stillettes also suitably packed. The packages shall be marked with the length, diameter, designation number (*see* Table 1) and the type of point of the needle and also the type of conical fitting, namely, Luer type.

11.2 Marking

The needle hub shall be suitably marked with the designated number corresponding to the outside diameter of the needle (*see* Table 1) and manufacturers identification mark.

11.2.1 *BIS Certification Marking*

The needle may also be marked with the Standard Mark.

11.2.1.1 The use of the Standard Mark is governed by the provision of the *Bureau of Indian Standards Act*, 1986 and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

12 SAMPLING

Sampling and acceptance criteria for hypodermic needles shall be as agreed to between the purchaser and the supplier. A recommended scheme for the same is given in Annex B.

ANNEX A

(*Clause* 10.2)

TEST FOR RESISTANCE OF NEEDLE TUBES TO BREAKAGE

A-1 Remove the needle tube from the hub. Rigidity fix on end of the needle tube.

A-2 Apply, at the distance given in Table 4, a force of sufficient magnitude to cause the needle tube to bend in one plane through and angle of ± 25°.

A-3 Perform 20 complete cycles of reversal of force and examine the tube visually for breakage.

Table 4 Resistance to Breakage (Reverse Bend Test)

(*Clause* A-2)

All dimensions in millimetres.

Sl No.	Nominal External Diameter	Distance Between Rigid Support and Point of Application of Bending Force
(1)	(2)	(3)
i)	0.40	10
ii)	0.45	10
iii)	0.50	10
iv)	0.55	15
v)	0.60	15
vi)	0.63	15
vii)	0.70 and 0.71	17.5
viii)	0.80	20
ix)	0.90 and 1.0	25
x)	1.10	27.5
xi)	1.20	30
xii)	1.25, 1.60, 2.0 and 2.5	[1]

Table 4 — *Concluded*

[1] Distance for these sizes shall be as agreed to between the manufacturer and the purchaser.

ANNEX B

(*Clause* 12)

SAMPLING PROCEDURE AND CRITERIA FOR CONFORMITY

B-1 LOT

B-1.1 In any consignment, all hypodermic needles of same shape and dimension and manufactured under similar conditions from the same raw material shall be grouped together to constitute a lot.

B-2 SELECTION OF SAMPLE

B-2.1 The number of needles to be selected from the lot shall depend upon the size of the lot and shall be in accordance with col 2 and 3 of Table 5. For lot size larger than 500, reference shall be made to IS 2500 (Part 1).

B-2.2 These needles shall be selected at random from the lot. In order to ensure randomness of selection, procedures given in IS 4905 may be followed.

B-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

B-3.1 The needles selected at random in accordance with col 3 of Table 5 shall be tested for shape and dimension (*see* **6.1** to **6.3**). Leakage test (*see* **10.4**), sharpness of needle point (*see* **10.5**) elasticity (*see* **10.6**), reverse bend test (*see* **10.7**), stiffness (*see* **10.1**), and security of swaging (*see* **10.8**). A lot shall be considered as conforming to these requirements, if the number of defectives found in the sample is less than or equal to the corresponding permissible number of defectives as given in col 4 of Table 5.

Table 5 Sample Size and Criteria for Conformity

Sl No.	Lot Size	Sample Size	Acceptance Number	Sub-Sample Size
(1)	(2)	(3)	(4)	(5)
i)	Up to 50	5	0	1
ii)	51 to 100	5	0	2
iii)	101 to 150	8	0	3
iv)	151 to 300	13	1	4
v)	301 to 500	20	1	5

B-3.2 If the lot is conforming to all the requirements as mentioned in **B-3.1**. The test for corrosion resistance (*see* **10.9**) and test for resistance to breakage (*see* **10.2**) shall be carried out on a sub-sample of size as given in col 5 of Table 5. If all the needles in the sub-sample pass the tests, the lot shall be considered as conformity to these tests.

B-3.3 The lot shall be considered as conforming to the standard, if conditions of **B-3.1** and **B-3.2** are satisfied.

ANNEX C

(Foreword)

COMMITTEE COMPOSITION

Medical Instruments and Disposables Sectional Committee, CHD 35

Organization	*Representative(s)*
Safdarjang Hospital, New Delhi	DR V H TALIB (*Chairman*)
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Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

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